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NOTICE OF ALLOWANCE AND FEE(S) DUE

25226 7590 04/16/2009

MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 04/16/2009

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

09/687,951

10/13/2000

Jeffrey L. Cleland

GEN02-002-US

8871

TITLE OF INVENTION: INJECTION VEHICLE FOR POLYMER-BASED FORMULATIONS

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO | \$1510 | \$0 | \$0 | \$1510 | 07/16/2009 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

25226 7590 04/16/2009

MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

| |
|--------------------|
| (Depositor's name) |
| (Signature) |
| (Date) |

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

09/687,951 10/13/2000 Jeffrey L. Cleland GEN02-002-US 8871

TITLE OF INVENTION: INJECTION VEHICLE FOR POLYMER-BASED FORMULATIONS

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|-------------|--------------|---------------|---------------------|----------------------|------------------|----------|
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nonprovisional NO \$1510 \$0 \$0 \$1510 07/16/2009

| EXAMINER | ART UNIT | CLASS-SUBCLASS |
|----------|----------|----------------|
|----------|----------|----------------|

KAM, CHIH MIN 1656 424-489000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 _____

2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/687,951 | 10/13/2000 | Jeffrey L. Cleland | GEN02-002-US | 8871 |
| 25226 | 7590 | 04/16/2009 | EXAMINER | |
| MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018 | | | KAM, CHIH MIN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1656 | |
| DATE MAILED: 04/16/2009 | | | | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

| | | | |
|-------------------------------|------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 09/687,951 | CLELAND ET AL. | |
| | Examiner | Art Unit | |
| | CHIH-MIN KAM | 1656 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/21/09.
2. ☒ The allowed claim(s) is/are 20,22,23,25-29,31,33,34,36,40-43,45-66 and 68-73.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/CB), Paper No./Mail Date <u>See Continuation Sheet</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|--|---|

/Chih-Min Kam/
 Primary Examiner, Art Unit 1656

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 11/2/07 (corrected copy).

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed on January 21, 2009 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 20, 22-23, 25-29, 31, 33, 34, 36, 40-43, 45-66 and 68-73 are pending.

Applicants' amendments filed November 17, 2008 and January 21, 2009 are acknowledged. Applicants' response has been fully considered. In the amendment filed November 17, 2008, claims 20, 22, 33, 34, 40-43, 48, 49, 55, 56, 61-66 and 68-73 have been amended, and claim 67 has been cancelled; and in the amendment filed January 21, 2009, claims 29 and 49 have been amended. Therefore, claims 20, 22-23, 25-29, 31, 33, 34, 36, 40-43, 45-66 and 68-73 are examined.

Withdrawn Claim Rejections - 35 USC § 112

3. The previous rejection of claims 20, 22-23, 25-29, 31, 36, 40-43, 45-66 and 68-73 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 10-11 of the amendment filed November 17, 2008 and at page 10 of the amendment filed January 21, 2009.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

4. The previous rejection of claims 22-23, 25-29, 31, 33, 34, 36, 42, 43, 45-47, 50-59 and 67-73 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-24 and 26-44 of co-pending application 11/614,462, is withdrawn in view of the obviousness-type double patenting rejection is only remaining rejection after the amendment filed January 21, 2009. Since the obviousness-type double patenting rejection is

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provisional and the instant application has an earlier filing date than that of 11/614,462, the rejection is withdrawn (see MPEP 804).

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Madeline Johnston on April 9, 2009.

Examiner's Amendment to the Claims:

Claims 20 and 31 have been amended as follows:

20. (Currently amended) A method for administering a biologically active agent, the method comprising:

injecting to an animal a formulation comprising:

(a) an injection vehicle comprising hyaluronic acid or sodium hyaluronate dissolved in a physiological buffer at a concentration of about 0.01 to about 3 percent weight per volume; and

(b) particles comprising:

(i) a first component that is the biologically active agent; and

(ii) a second component that is a biocompatible polymeric matrix,

wherein the concentration of the polymeric matrix is about 100 mg/mL to about 500 mg/mL of the formulation, and further wherein the hyaluronic acid or sodium hyaluronate is at a concentration sufficient to inject the formulation through a 23-gauge or smaller bore needle.

31. (Currently amended) The injectable formulation of claim 22, wherein the concentration of the particles in the formulation is about + 100 mg/mL to about 300 mg/mL.

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The following is an Examiner's Statement of Reasons for Allowance: The following references appear to be the closest art to the claimed invention. Suzuki *et al.* (US Patent 6,197,326) teach an intra-articular preparation for the treatment of arthropathy, which comprises microcapsules of a biocompatible, high molecular weight substance such as PLGA, homopolymer or copolymer of lactic acid, glycolic acid and caprolactone, and a drug such as cyclosporin; and the microcapsules can be administered in the form of injection by suspending it in a dispersion medium such as water, where a buffer, NaCl, hyaluronic acid, or chondroitin sulfate or salts thereof can be added. However, Suzuki *et al.* does not teach the concentration of hyaluronic acid is about 0.01 to about 3% (w/v) in a physiological buffer, and the concentration of the particle is about 100 mg/mL to about 500 mg/mL of formulation. Igari *et al.* (US Patent 5,416,071) teach a pharmaceutical composition suitable of injection comprising erythropoietin (Examples 1-11) or other biological agents such as NGF (Example 12) and hyaluronic acid, where hyaluronic acid, a high molecular weight compound which is known to be biodegradable and pharmacologically injectable at the concentration of 0.01 to 3% (weight to volume). However, Igari *et al.* is silent on the microcapsule component such as a polymeric matrix used in the formulation. Since the two references either alone or combined do not teach or suggest the injectable formulation comprising (a) an injection vehicle comprising hyaluronic acid or sodium hyaluronate dissolved in a physiological buffer at a concentration of about 0.01 to about 3% (w/v), and (b) a particle comprising a biologically active agent and a biocompatible polymeric matrix, where the concentration of the polymeric matrix is about 100 mg/mL to about 500 mg/mL of formulation, and wherein the hyaluronic acid or sodium hyaluronate is at a concentration sufficient to inject the formulation through a 23-gauge or smaller bore needle; and a method for administering such injectable formulation. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

April 9, 2009